

Appl. No. : **10/638,173**
Filed : **August 6, 2003**

REMARKS

Claims 60-93 are currently pending and presented for examination. After carefully considering the instant Office Action, Applicants respectfully traverse the Examiner's rejection of these claims.

Rejection of claims 60-93 under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 60-93 under 35 U.S.C. § 112, first paragraph, as not being adequately described because the application allegedly "contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention." In particular, the Examiner asserts that the application fails to provide support for a "non-permanent sealant" as recited in the claims because the specification allegedly "only discloses the use of rubber or silicon partitions between assay locations rather than any non-permanent sealant."

Applicants maintain that the specification adequately supports the limitation "non-permanent sealant" as used in independent claims 60, 71 and 83. To demonstrate this support, Applicants respectfully ask the Examiner to re-consider the language present in the specification at page 10, lines 1-24. For the Examiner's convenience, this section of the specification is reproduced below.

Appl. No. : 10/638,173
Filed : August 6, 2003

However, the assay locations, need not be limited to wells of a microtiter plate. That is, any separable location on a substrate serves as an assay location. By separable location means a location on a substrate that is physically separated from other regions on the substrate. The physical separation can be any border between assay locations. The separation can be a partition, alternatively, the separation can simply be spacing between assay locations sufficient at least to distinguish one from the other. When it is desired to maintain separate solutions in each assay location, there need only be sufficient separation such that reagents delivered to one assay location will not cross contaminate another assay location. However, in some embodiments, such a physical barrier is not necessary, or in some instances, not even desired. As such, the assay locations need only be separated enough to distinguish one from the other. When partitions or borders are used between assay locations, preferred borders include but are not limited to hydrophobic regions surrounding an assay location; ridges or rims of sufficient width and height to prevent sample migration between assay locations; or troughs of sufficient width and depth to prevent sample migration between assay locations. In some embodiments, the borders are made of gaskets including, but not limited to rubber or silicon. That is, in a preferred embodiment, the border comprises a sealing mechanism to prevent leakage of the sample or reagents between wells of the substrate. As will be appreciated by those in the art, this may take on a variety of different forms. In one embodiment, there is a gasket on the substrate comprising the array, comprising sheets, tubes or strips. Alternatively, there may be a rubber or silicon strip or tube used. In one embodiment the substrate contains an indentation or channel into which the gasket fits. Furthermore, adhesives can be used to attach the gasket to the substrate. When hydrophobic regions are used to surround an assay location, the hydrophobic regions effectively contain or force the solutions to localize over the sites contained within the region surrounded by the hydrophobic region. In some embodiments the borders or partitions are made of printable materials including, but not limited to gels.

See U.S. Patent Application No: 10/638,173, page 10, lines 1-24.

The paragraph set forth above describes a variety of non-permanent sealants useful for separating assay locations. At lines 3-4, the above paragraph begins by stating that “[t]he physical separation can be any border between assay locations.” (emphasis added). The excerpted paragraph, at lines 10-13, goes on to state that “[w]hen partitions or borders are used between assay locations, preferred borders include but are not limited to hydrophobic regions surrounding an assay location” At lines 13-14, this paragraph describes certain embodiments wherein the borders are “gaskets including, but not limited to rubber or silicon.” (emphasis added). The paragraph further states that “[i]n a preferred embodiment, the border comprises a sealing mechanism . . . [that] may take on a variety of different forms. In one embodiment, there is a gasket on the substrate . . . [a]lternatively, there may be a rubber or silicon strip or tube used.” (see lines 15-19, emphasis added). When read together, lines 1-19 of the

Appl. No. : 10/638,173
Filed : August 6, 2003

above paragraph establish that a variety of different sealing borders can be used, which include, but are not limited to, rubber and silicon-based materials, such as rubber and silicon gaskets.

The remainder of the above paragraph demonstrates that non-permanent sealants may be employed as borders or partitions between assay locations. For instance, line 20 of this paragraph indicates that “adhesives can be used to attach the gasket to the substrate,” thereby indicating that sealants can be either permanently or non-permanently attached to substrate. The paragraph then goes on to describe hydrophobic regions surrounding the assay locations and at line 24, it states that borders or partitions can be “made of printable materials including, but not limited to gels.” Applicants respectfully submit that, when viewed in its entirety, the instant specification, and particularly the disclosure at page 10, lines 1-24, provides sufficient description such that one of ordinary skill in the art would immediately recognize that non-permanent sealant materials that are useful in the composite arrays include hydrophobic borders, such as rubber gaskets, rubber strips, rubber tubes, silicon gaskets, silicon strips, silicon tubes and various gels. Applicants further submit that, when contemplating the use of gels as taught in the specification, a skilled artisan would immediately envision the use of petroleum jelly, silicon sealants, soft waxes, acylated polyols and any other flexible, printable gel-like materials known at the time of filing the instant specification.

In view of the foregoing remarks, Applicants respectfully submit that the specification does provide support for a “non-permanent sealant” as recited in independent claims 60, 71 and 83. As such, Applicants respectfully request that the rejection of claims 60-93 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection of claims 60-93 under 35 U.S.C. § 103(a)

The Examiner rejects independent claims 60, 71, and 83 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,232,066 (Felder et al.) in view of U.S. Patent No. 6,023,540 (Walt et al.). In particular, the Examiner asserts that Felder et al. disclose all of the elements of the independent claims except for depressions “being configured to contain a single microsphere.” The Examiner then asserts that Walt et al. teach this missing element and that a skilled artisan would be motivated to combine the teachings of these two references because

Appl. No. : **10/638,173**
Filed : **August 6, 2003**

Walt et al. allegedly teach that a single-bead “configuration is important for ensuring that light from each microsphere and reactions occurring on the microsphere are individually detected.”

Applicants maintain that claims 60-93 are not obvious in view any of the above-cited references or combinations thereof. In particular, Applicants respectfully submit that the remarks set forth in the instant Office Action do not establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Finally, the prior art reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The remarks set forth in the instant Office Action fail to establish a motivation to combine the teachings of Walt et al. with the teachings of Felder et al. When evaluating whether there exists motivation to combine or modify the teachings of the primary reference, it is well established that it is improper to combine references where the references teach away from their combination. *See In re Grasselli*, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983). The Court of Appeals for the Federal Circuit has stated that a reference teaches away if a “person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 31 U.S.P.Q. 2d 1130, 1131 (Fed. Cir. 1994). Furthermore, when the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

Felder et al. teach away from combining the fiber optic arrays disclosed by Walt et al. with the arrays disclosed in Felder et al. because the arrays disclosed therein require a plurality of anchors located at each test region. For example, Felder et al. at column 8, lines 16-38, describes the relationship of anchors to each assay position on the disclosed arrays. In particular, this paragraph explains that the disclosed device operates on a pattern recognition system. In such a system, the location of each individual anchor within a test region of the array is derived from its relative position within the overall pattern of anchors in that region. As the specification explains, such a system can only work if “the area used by each assay position (the area of the

Appl. No. : **10/638,173**
Filed : **August 6, 2003**

droplet or the area of the *well* for example) is large enough to be certain to contain at least one whole unit of the repeating *pattern of anchors*" (column 8, lines 31-38; emphasis added). Put another way, for the device disclosed by Felder et al. to work, each test region must include a plurality of anchors: "at least two, but preferably more, anchors per region" (column 7, lines 42-43). In view of this disclosure, Felder et al. teaches away from adapting the devices disclosed therein to utilize the single-bead-per-well configuration of Walt et al. because the single-bead-per-well configuration provides no recognizable pattern of anchors within a well (assay position) as required by devices disclosed in Felder et al. In fact, combining the teachings of Felder et al. with those of Walt et al. would render Felder et al. unsuitable for its intended purpose. As such, a skilled artisan would not be motivated to adapt the teachings of Felder et al. to incorporate the single-bead-per-well configuration of Walt et al.

For at least the foregoing reasons, Applicants submit that one of ordinary skill in the art would not combine Felder et al. and Walt et al., to arrive at the invention set forth in independent claims 60, 71, and 83, and thus, these claims are not obvious in view of the combination of the two recited references. Claims 61-70, 72-82, and 84-93 depend from independent claims 60, 71, and 83, respectively. As such, Applicants respectfully request that the rejection of claims 60-93 under 35 U.S.C. § 103(a) be withdrawn.

Obviousness-type double patenting rejection of claims 60-93

The Examiner has rejected claims 60-93 under the judicially-created doctrine of obviousness-type double patenting. The Examiner asserts that claims 60-93 are obvious over claims 1-30 of U.S. Patent No. 6,429,027 (the '027 Patent) in view of Felder et al. Additionally, the Examiner alleges that claims 60-93 are obvious over claims 1-21 of U.S. Patent No. 6,998,274 (the '274 Patent) in view of Felder et al.

The Examiner first asserts that the open claim language of the instant claims encompasses the additional elements of the '027 and '274 patents, respectively. The Examiner next asserts that the "non-permanent sealant" feature of the instant claims, which is not recited in either of the '027 or '274 patents, is an obvious improvement in view of Felder et al.

Applicants disagree that claims 60-93 are obvious over either claims 1-30 of the '027 Patent or claims 1-21 of the '274 Patent in view of Felder et al. However, in order to expedite

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Appl. No. : **10/638,173**
Filed : **August 6, 2003**

the allowance of the currently pending claims, Applicants are filing a terminal disclaimer herewith.

In view of the terminal disclaimer, Applicants respectfully request that the Examiner withdraw the obviousness-type double patenting rejections of claims 60-93.

CONCLUSION

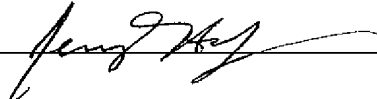
Applicants believe that all outstanding issues in this case have been resolved and that the present claims are in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite the resolution of such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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